

6248.200-US
US Patent Application No. 10/068,224

Page 2 of 11

AMENDMENTS TO THE CLAIMS

The following Listing of Claims replaces all prior versions, and listings, of claims in this Application.

LISTING OF CLAIMS

1. (previously presented) A composition comprising a meiosis activation substance in a container wherein the oxygen content in the container is less than about 0.01 moles oxygen per liter and the container is capable of maintaining the oxygen content.

2. (cancelled)

3. (previously presented) The composition of claim 1, wherein the oxygen content is less than about 0.001 moles of oxygen per liter.

4. (previously presented) The composition of claim 1, wherein the oxygen content is less than about 0.0001 moles of oxygen per liter.

5. (currently amended) A composition product comprising (A) a container capable of maintaining a low oxygen content and (B) a pharmaceutical composition contained therein that comprises comprising (i) a solid composition of a meiosis activation substance, and (ii) an additive, and (iii) wherein the pharmaceutical composition is contained in an atmosphere with an oxygen content of less than 10% contained therein, wherein the container is capable of maintaining the oxygen content.

6. (currently amended) The product composition of claim 5, wherein the solid composition of a meiosis activation substance has a high aqueous solubility.

6248.200-US
US Patent Application No. 10/068,224

Page 3 of 11

7. (cancelled)

8. (currently amended) The composition of product of claim 5, wherein the oxygen content of the atmosphere is less than 5%.

9. (currently amended) The composition of product of claim 8, wherein the oxygen content of the atmosphere is less than 1%.

10. (currently amended) The composition of product of claim 5, wherein the atmosphere contains more than 90% nitrogen or argon.

11. (currently amended) The composition of product of claim 10, wherein the atmosphere contains more than 99% nitrogen or argon.

12. (currently amended) The composition of product of claim 5, wherein the solid meiosis activation substance composition has a water content of less than about 10%.

13. (currently amended) The composition of product of claim 12, wherein the solid meiosis activation substance composition has a water content of less than about 5%.

14. (currently amended) The composition of product of claim 13, wherein the solid meiosis activation substance composition has a water content of less than about 1%.

15. (currently amended) The composition of product of claim 5, wherein the solid meiosis activation substance composition has an organic solvent content of less than about 10%.

6248.200-US
US Patent Application No. 10/068,224

Page 4 of 11

16. (currently amended) The composition claim 15, wherein the solid meiosis activation substance composition has an organic solvent content of less than about 5%.

17. (currently amended) The composition of product of claim 16, wherein the solid meiosis activation substance composition has an organic solvent content of less than about 1%.

18. (currently amended) The composition of product of claim 5, wherein the meiosis activation substance content makes up less than about 10% of the pharmaceutical composition contained in the container by weight.

19. (currently amended) The composition of product of claim 18, wherein the meiosis activation substance makes up less than about 2% of the pharmaceutical composition contained in the container by weight.

20. (currently amended) The composition of product of claim 19, wherein the meiosis activation substance makes up less than about 1% of the pharmaceutical composition contained in the container by weight.

21. (previously presented) The composition of claim 1, wherein the meiosis activation substance is a compound exhibiting a percentage germinal vesicle breakdown which is 50% higher than a control.

22. (previously presented) The composition of claim 1, wherein the meiosis activation substance is 4,4-dimethyl-5 α -cholest-8,14,24-triene-3 β -ol; 4,4-dimethyl-5 α -cholest-8,14,24-trien-3 β -ol hemisuccinate; 5 α -cholest-8,14-dien-3 β -ol; 5 α -cholest-8,14-dien-3 β -ol hemisuccinate; (20S)-cholest-5-en-3 β ,20-diol; 3 β -hydroxy-4,4-dimethyl-5 α -chola-8,14-dien-24-oic acid-N-(methionine) amide; cholest-5-en-16 β -ol; or (20S)-20-[(piperidin-1-yl)methyl]-4,4-dimethyl-5 α -pregna-8,14-dien-3 β -ol.

6248.200-US
US Patent Application No. 10/068,224

Page 5 of 11

23. (currently amended) The composition of product of claim 5, wherein the additive is a protein or a phosphoglyceride.

24. (currently amended) The composition of product of claim 23, wherein the additive is serum albumin.

25. (currently amended) The composition of product of claim 24, wherein the serum albumin is human serum albumin or recombinant human serum albumin.

26. (currently amended) The composition of product of claim 5, wherein the additive makes up at least about 90% of the content of the pharmaceutical composition contained in the container.

27. (currently amended) The composition of product of claim 26, wherein the additive makes up at least about 98% of the pharmaceutical composition contained in the container.

28. (currently amended) The composition of product of claim 27, wherein the additive makes up at least about 99% of the pharmaceutical composition contained in the container.

29. (currently amended) The composition of product of claim 5, wherein the container comprises more than one or more hollow space spaces and at least one of the hollow spaces contains the pharmaceutical composition a composition comprising (i) a solid composition a meiosis activation substance with a high aqueous solubility, (ii) the additive, and (iii) the atmosphere.

6248.200-US
US Patent Application No. 10/068,224

Page 6 of 11

30. (currently amended) A product comprising (A) a container and (B) a pharmaceutical composition contained therein that comprises ~~The composition of claim 5, wherein an aqueous media is added to the solid composition to form an aqueous solution (i) a solid meiosis activation substance and (ii) an additive, wherein the pharmaceutical composition forms a solution comprising a dissolved form of the meiosis activation substance upon sufficient contact with an aqueous medium.~~

31. (currently amended) The composition of method of claim 30 42, wherein the meiosis activation substance in the aqueous solution is in a concentration of at least about 100 μ g/ml.

32. (currently amended) The composition of method of claim 30 42, wherein the meiosis activation substance in the aqueous solution is in a concentration of at least about 10 μ g/ml.

33. (currently amended) The composition of method of claim 30 42, wherein the meiosis activation substance in the aqueous solution is in a concentration of at least about 1 μ g/ml.

34. (currently amended) The composition of method of claim 30 42, wherein the meiosis activation substance in the aqueous solution is in a concentration of at least about 0.001 μ g/ml.

35. (currently amended) The composition of method of claim 30 42, wherein the aqueous media has an organic solvent content of less than about 0.1%.

36. (currently amended) The composition of method of claim 35, wherein the aqueous media has an organic solvent content of less than about 0.05%.

6248.200-US
US Patent Application No. 10/068,224

Page 7 of 11

37. (original) A process for preparing a pharmaceutical composition in a closed container, comprising:

- a) preparing a solid composition comprising a meiosis activation substance and an additive;
- b) adding the solid composition to the container;
- c) freeze drying the composition; and
- d) closing the container *in vacuo*.

38. (previously presented) The process of claim 37, wherein the preparation of the solid composition is performed *in vacuo*.

39. (previously presented) The process according to claim 37, wherein the preparation of the solid composition is performed in an atmosphere having an oxygen content of less than about 0.01 moles per liter.

40. (previously presented) A process for preparing a pharmaceutical composition in a closed container comprising:

- a) preparing a solid composition comprising a meiosis activation substance and an additive;
- b) filling the solid composition into the container;
- c) filling the container with an atmosphere having an oxygen content of less than 10%; and
- d) closing the container.

41. (previously presented) The process of claim 40, wherein the solid composition is prepared in an atmosphere having an oxygen content of less than about 0.01 moles per liter.

42. (previously presented) A process for increasing the stability of a composition in a closed container comprising:

- a) preparing a solid composition comprising a meiosis activation substance having an oxygen content of less than about 0.01 moles per liter and an additive;

6248.200-US
US Patent Application No. 10/068,224

Page 8 of 11

- b) filling the solid composition into the container;
- c) filling the container with an atmosphere having an oxygen content of less than 10%; and
- d) closing the container.

43. (new) A method for preparing a solution comprising a meiosis activating substance comprising:

- a) providing a container containing a pharmaceutical composition comprising a solid meiosis activating substance and an additive; and
- b) contacting the pharmaceutical composition with an aqueous medium so as to form an aqueous solution comprising a dissolved form of the solid meiosis activating substance.

44. (new) The method of claim 43, wherein the pharmaceutical composition is maintained in the container in a closed state in an atmosphere with an oxygen content of less than 10% prior to contact with aqueous medium.

45. (new) The method of claim 44, wherein (a) the aqueous medium has an organic solvent content of less than about 0.1%; (b) the meiosis activating substance in the aqueous solution is in a concentration of at least about 100 μ g/ml; or (c) the aqueous medium has an organic solvent content of less than about 0.1% and the meiosis activating substance in the aqueous solution is in a concentration of at least about 100 μ g/ml.